

DEPARTMENT OF HEALTH SERVICES

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March 20, 1998

**MMCD Policy Letter 98-06**

TO: [X] County Organized Health System
 [X] Geographic Managed Care Plans
 [X] Prepaid Health Plans
 [X] Primary Care Case Management

SUBJECT: NEWBORN AND PRENATAL GENETIC SCREENING SERVICES

BACKGROUND

State law requires that all women seen for prenatal care prior to 20 weeks gestation be offered prenatal blood testing in the Department of Health Services' (DHS) expanded alpha-fetoprotein (AFP) program and that all newborns be screened for certain treatable heritable disorders. DHS' Genetic Disease Branch administers the newborn and prenatal screening programs. Initial newborn and prenatal genetic screening laboratory services are provided through a network of state-approved laboratories supported by area genetics centers.

GOAL

To assure that pregnant women and newborns are provided timely and effective genetic disease prevention, early detection and diagnosis, treatment and education and counselling services.

POLICY**I. Newborn Screening**

State law [California Code of Regulations (CCR), Title 22, Sections 51348.1, 51529 (d) and CCR, Title 17, Sections 6500 through 6510] requires all newborns to be screened for a series of treatable heritable disorders (PKU, galactosemia, hypothyroidism, sickle cell disease, and related hemoglobinopathies) prior to discharge from the hospital of birth. Plans are responsible for implementing procedures to ensure that perinatal care providers appropriately obtain the required blood specimens from all newborns, using DHS approved specimen collection forms. Specimens must

be submitted to DHS approved laboratories only (see Attachment 1). Follow-up tests requested by the Newborn Screening (NBS) program are also done by these DHS approved laboratories. The fee currently charged by DHS for initial and necessary follow-up tests is \$42, as set by regulation (CCR, Title 17, Section 6508) and is charged to the hospital of birth. For out of hospital births, the attending physician or midwife is billed. Plans are capitated for these charges and are responsible for reimbursement arrangements with affected network perinatal service providers, since these providers are no longer able to separately bill Medi-Cal fee-for-service (FFS) for reimbursement.

The area genetics center notifies the infant's primary care physician (PCP) of record of an initial presumptive positive test result and of the results of follow-up tests. Newborns with confirmed positive tests are California Children Services (CCS) eligible and the plan should assure that these infants are referred to the appropriate county CCS office. The plan remains responsible for the provision of all non-CCS related medical services for the member and for coordination of care with the CCS program.

II. Prenatal Screening

State law requires that all women seen for prenatal care prior to 20 weeks gestation be offered screening blood tests for the detection of individuals at increased risk for carrying a fetus with certain heritable and congenital disorders. The prenatal care provider should offer screening tests to the pregnant member at the first prenatal visit. Testing occurs through DHS' Expanded AFP Program (CCR, Title 17, Sections 6521 through 6532), which currently offers triple marker screening. Triple marker screening tests the woman's serum for AFP, unconjugated estriol (UE) and human chorionic gonadotrophin (HCG). The risk for open neural tube defects, abdominal wall defects, trisomy 21 (Down Syndrome) and trisomy 18 are estimated based on the woman's age and serum values. Only laboratories designated by DHS may be used for this test. A member's participation in the Expanded AFP Program is voluntary. The member's consent or refusal to participate must be documented.

A regional Expanded AFP coordinator will call the prenatal care provider if the test result is screen positive. For women with positive tests who are at high risk of a birth defect, the Expanded AFP Program provides follow-up diagnostic services. These services are offered through State-approved Prenatal Diagnosis Centers (PDC) (see Attachment 2) and include genetic counseling, amniocentesis, and amniotic fluid analysis including karyotype.

Triple marker testing and necessary follow-up services are "carved-out" of plan's contracts and must be billed FFS. Plans must assure that their perinatal providers

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understand how to participate in and access this system for members, in accordance with regulations. Prenatal care providers should be directed to enter the patients' Medi-Cal number on the test request form provided by the State in the billing information space. The Expanded AFP Program will then bill Medi-Cal directly. Except for the services provided under the Expanded AFP Program, plans remain responsible for the provision of all necessary medical services for the pregnant member, including any amniocentesis believed by plan providers to be medically necessary, regardless of the results of the Expanded AFP tests. Some women over age 35 may decide not to use the Expanded AFP Program and opt instead to request a diagnostic amniocentesis. The plan is responsible for authorizing and providing this procedure.

III. Member Education

The plan must implement procedures which assure that pregnant members are informed that newborns must be screened for certain treatable hereditary disorders. State law (CCR, Title 17, Section 6504) requires that all perinatal care providers provide pregnant women with a copy of DHS' document titled "Important Information for Parents," which contains information concerning newborn screening.

The Expanded AFP Program has developed patient education booklets for women under 35 years of age at term and for women 35 years of age and older at term. These booklets are to be given at the first prenatal visit to all pregnant women who are seen before the 20th gestational week in order to help them choose whether or not to voluntarily participate in the Expanded AFP Program; to select a diagnostic test or to forego both options. A member must be informed that her participation in the program is voluntary and her decision to participate or not to participate must be documented. Plan perinatal providers must coordinate their services with the follow-up services provided by the Expanded AFP Program.

Translated materials, in the appropriate threshold and concentration standard languages, should be available to plan members. If the materials are unavailable in the member's language, the information should be read to the member.

IV. Provider Training

Plans must ensure that network providers delivering perinatal and/or pediatric services and relevant support staff are knowledgeable regarding the requirements of the Newborn Screening Program and the Expanded AFP Program. Network providers are required to follow all State laws governing the provision of newborn screening and expanded AFP services, including complying with all mandated genetic disorder

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reporting requirements. A copy of the most current CCR sections governing these services, including reporting requirements, is enclosed with this policy letter. (see Attachment 3).

DISCUSSION

DHS' Genetic Disease Branch administers several other programs, in addition to the Newborn Screening Program and Expanded AFP Programs. These include, but are not limited to, the Tay-Sachs Disease Prevention Program and the Maternal PKU Program. In addition, the State Genetic Disease Laboratory provides, at no charge, phenylalanine blood tests to monitor the medically required low phenylalanine diet for treatment of PKU. Plans are encouraged to educate network providers regarding the services and materials available through DHS' Genetic Disease Branch.

If there are any questions regarding this policy letter, please contact your contract manager.



Ann-Louise Kuhns, Chief
Medi-Cal Managed Care Division

Enclosures

Attachment 1

**Newborn
Screening
Panel**

All newborns must be screened for preventable forms of mental retardation under regulations issued by the Department of Health Services (17, CCR, 6500). The Department of Health Services, Genetic Disease Branch, has contracted with six clinical laboratories to perform the required tests on Medi-Cal recipients. The designated screening panel consists of the following laboratory tests:

1. Radioimmune assay for T4
2. Radioimmune assay for TSH
3. Qualitative fluorometric blood phenylalanine
4. Galactose - 1- uridyltransferase
5. Microbial inhibition assay for blood galactose

The laboratories listed below perform these tests and are reimbursed under contract by the Genetic Disease Branch.

The designated testing laboratories are:

Western Clinical Laboratory
408 Sunrise Avenue
Roseville, CA 95678

American Clinical Laboratory
10477 - C Roselle Street
San Diego, CA 92121

Allied Medical Laboratory
20392 Town Center Lane
Cupertino, CA 95014

Reference Laboratory
1011 Rancho Conejo Blvd.
Newbury Park, CA 91320

Fresno Community Hospital
and Medical Center
Fresno and "R" Streets
Fresno, CA 93715

Memorial Hosp. of Long Beach
2801 Atlantic Avenue
Long Beach, CA 90806

Attachment 2

Prenatal Diagnosis Centers and Satellite Locations*

State-approved for Expanded AFP Follow-up

Southern California

Alfigen/The Genetics Institute

Pasadena
(818) 666-3300

Santa Barbara, San Luis Obispo, Palm Springs, Bakersfield, Pomona, Los Angeles, Tarzana, Ventura, Torrance, West Covina, Whittier, Long Beach, Inglewood, Monterey Park, Garden Grove, Santa Maria, San Diego, Irvine

Cedars-Sinai Medical Center

Los Angeles
(310) 855-2214
Van Nuys

Childrens Hospital of Los Angeles

Los Angeles
(213) 669-2478

Genesis Laboratories

Redlands
(909) 335-5610

Genetics Center

Orange
(714) 667-0878
Irvine, Mission Viejo, Bakersfield

Genzyme Genetics

Long Beach
(800) 745-4363 x 7011

Laguna Hills, Newport Beach, Torrance, Anaheim, Thousand Oaks, Ventura, Fountain Valley, Lancaster, Tarzana, Inglewood, Palm Springs

Kaiser Permanente

Panorama City
(626) 564-3322

Bellflower, Fontana, Harbor City, Los Angeles, Anaheim, Riverside, West LA, Woodland Hills, Baldwin Park, San Diego

King Drew Prenatal Diagnosis Center

Los Angeles
(310) 668-4620
Lynwood

LA County/USC Medical Center

Los Angeles
(213) 226-3256

Loma Linda University Medical Center

Loma Linda
(909) 478-6505

Riverside, La Mirada, Fountain Valley, Victorville

Prenatal Diagnosis Center of Southern California

Beverly Hills
(310) 652-5884

Prenatal Diagnostic & Perinatal Center

San Bernardino
(909) 881-4503

Apple Valley, Indio, Riverside, Corona, Wildomar, Montclair, Pasadena, West Covina, Burbank, Oceanside, Loma Linda

Sharp/Children's Prenatal Diagnosis Center

San Diego
(619) 541-6860

U.C. Irvine

Orange
(714) 456-5780
Santa Ana

U.C.L.A. Medical Center

Los Angeles
(310) 825-0300
Northridge, Sylmar, Santa Barbara, Santa Monica

U.C. San Diego

La Jolla
(619) 597-2600
El Centro

Northern California

Alfigen/The Genetics Institute

(408) 559-2258
San Jose, Monterey, Salinas, Walnut Creek

Alta Bates Perinatal Center

Oakland
(510) 204-5359

California Pacific Medical Center

San Francisco
(415) 750-6400
Greenbrae, Santa Rosa

East Bay Perinatal/Children's Hospital

Oakland
(510) 653-3335
Walnut Creek, San Ramon

Genzyme Genetics

(408) 885-7925
San Jose

Kaiser Permanente

Oakland
(510) 596-6298
Sacramento, San Francisco, San Rafael, San Jose, Hayward

Prenatal Diagnosis of Northern California

Sacramento
(916) 736-6888
Stockton, Fairfield, Modesto

Prenatal Diagnostics, Inc.

Mountain View
(415) 964-1505
Los Gatos, Palo Alto, San Mateo, Fremont, Salinas, San Jose

Stanford University

Stanford
(415) 723-5198
Mountain View

Sutter Prenatal Diagnosis Center

Sacramento
(916) 733-1900

U.C. Davis

Sacramento
(916) 734-6124
Carmichael, Davis, Redding

U.C. San Francisco

San Francisco
(415) 476-4080
Corte Madera, Santa Rosa

Valley Children's Hospital

Fresno
(209) 243-6633

*Subject to change

Expanded AFP Coordinator Offices

Northern California

San Francisco

(415) 476-1692

Fax (415) 502-0867

Sacramento

(916) 734-6575

Fax (916) 734-6025

Oakland

(510) 428-3769

Fax (510) 450-5874

Palo Alto

(415) 723-6894

Fax (415) 725-2878

Fresno

(209) 225-5108

Fax (209) 225-8561

Kaiser Permanente

(510) 596-6190

Fax (510) 596-6800

Southern California

Los Angeles

(310) 855-2154

Fax (213) 653-9655

Los Angeles

(213) 221-5606

Fax (213) 224-0340

Los Angeles (Torrance)

(310) 212-0816

Fax (310) 782-7704

Los Angeles, Ventura,

Santa Barbara

(310) 206-8211

Fax (310) 794-1290

Orange

(714) 456-5994

Fax (714) 456-7817

Riverside/San Bernardino

(909) 890-3123

Fax (909) 890-3120

San Diego

(619) 822-1280

Fax (619) 822-1284

Kaiser Permanente

(626) 564-3322

Fax (626) 564-3311

An Expanded AFP coordinator office phone number is listed on all result mailers.

Call (510) 540-2534 for questions.

Attachment 3

HISTORY

- Amendment of subsection (b)(3) filed 4-15-80 as an emergency; effective upon filing (Register 80, No. 16). A Certificate of Compliance must be transmitted to OAH within 120 days or emergency language will be repealed on 8-14-80.
2. Certificate of Compliance transmitted to OAL 7-29-80 and filed 8-20-80 (Register 80, No. 34).
 3. Amendment of subsection (a), new subsections (a)(1)-(3), and amendment of subsection (b)(3) and NOTE filed 3-29-96; operative 4-28-96 (Register 96, No. 13).
 4. Editorial correction of subsection (b)(3) (Register 97, No. 12).
 5. Amendment of subsection (b)(3) and NOTE filed 5-22-97 as an emergency; operative 5-22-97 (Register 97, No. 21). A Certificate of Compliance must be transmitted to OAL by 9-19-97 or emergency language will be repealed by operation of law on the following day.

Subchapter 8.1. Immunization Against Measles (Rubeola)

HISTORY

1. Repealer filed 3-22-78 as an emergency; effective upon filing (Register 78, No. 12). For prior history, see Registers 67, No. 43; 67, No. 48; and 72, No. 11.

Subchapter 8.2. Immunization Against Diphtheria, Tetanus, and Pertussis

HISTORY

1. Repealer filed 3-22-78 as an emergency; effective upon filing (Register 78, No. 12). For prior history, see Register 72, No. 11.

Subchapter 9. Heritable Diseases

Article 1. Testing for Preventable Heritable Disorders

§ 6500. Definitions.

(a) **Preventable Heritable or Congenital Disorders.** "Preventable heritable or congenital disorders" means any disorder or abnormality present at birth which is detectable by testing a newborn and for which effective means of prevention or amelioration exist.

(b) **Newborn.** "Newborn" means an infant 30 days of age and under.

(c) **Birth Attendant.** "Birth attendant" means any person licensed or certified by the State to provide maternity care and to deliver pregnant women or to practice medicine.

(d) **Perinatal Licensed Health Facility.** "Perinatal licensed health facility" means any health facility licensed by the State and approved to provide perinatal, delivery, newborn intensive care, newborn nursery or pediatric services.

(e) **Days of Age.** "Days of age" means the measurement of the age of a newborn in 24-hour periods so that a newborn is one day of age 24 hours following the hour of birth.

(f) **Discharge.** "Discharge" means release of the newborn from care and custody of the perinatal licensed health facility to the parents or into the community.

(g) **Transfer.** "Transfer" means release of the newborn from care and custody of one perinatal licensed health facility to care and custody of another perinatal licensed health facility, or admission to another perinatal licensed health facility of a newborn in an out-of-state facility.

(h) **Newborn's Physician.** "Newborn's physician" means the physician responsible for the care of the newborn after discharge from the hospital.

(i) **Initial Specimen.** "Initial specimen" means the first specimen collected subsequent to birth, pursuant to these regulations.

(j) **Initial Test.** "Initial test" means the first valid newborn screening test or combination of tests of a newborn for each disorder covered by these regulations.

(k) **Initial Presumptive Positive Test.** "Initial presumptive positive test" means a newborn's blood specimen which is defined as positive for reporting purposes.

(l) **Inadequate Specimen.** "Inadequate specimen" means a newborn's blood specimen which is not suitable in quality or quantity to perform newborn screening for one or more of the disorders covered by these regulations.

(m) **Repeat Specimen.** "Repeat specimen" means a specimen collected from a newborn following the newborn screening laboratory's report that a previously collected specimen was either inadequate or that test results were inconclusive.

(n) **Repeat Test.** "Repeat test" means a test required by these regulations to be repeated for a newborn because the previous specimen or test results were inadequate or test results were not complete.

(o) **Recall Specimen.** "Recall specimen" means a specimen collected from a newborn because the initial test or combination of tests was presumptive positive for any of the disorders covered by these regulations.

(p) **Recall Test.** "Recall test" means a test ordered collected from a newborn because the initial test or combination of tests was presumptive positive for any of the disorders covered by these regulations.

(q) **Newborn Screening Laboratory.** "Newborn screening laboratory" means a laboratory operated by the Department or a laboratory contracting with the Department to conduct tests required by this article.

(r) **Area Genetic Center.** "Area genetic center" means an institution, corporation, hospital or university medical center having specialized expertise designated by the Department to serve a specific geographic area of the State which has contracted with the Department to provide follow-up, referral and diagnosis of a preventable heritable or congenital disorder as defined in this Article.

(s) **Sickle Cell Education and Counseling Program.** "Sickle cell education and counseling program" means an educational and counseling program in which the disease orientation is, in whole or in major part, sickle cell disease.

(t) **Sickle Cell Counselor.** "Sickle cell counselor" means a person who provides face to face information on the medical, social, and genetic consequences of sickle cell disease and trait and who has successfully completed an approved sickle cell counselor training program and is certified as such by the Department of Health Services. Physicians and individuals with a master's degree in genetic counseling who are board eligible or board certified by the American Board of Medical Genetics are not required to complete such a training program.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 309, 325, 326 and 327, Health and Safety Code.

HISTORY

1. New subchapter 9 (section 6500) filed 12-1-65; designated effective 1-1-66 (Register 65, No. 23).
2. Amendment filed 10-5-66; effective thirtieth day thereafter (Register 66, No. 34).
3. Repealer filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
4. Renumbering and amendment of former section 6500.5 to section 6500 filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
5. Amendment of subsection (r) and new subsections (s) and (t) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).
6. Amendment of subsection (t) filed by the Department of Health Services with the Secretary of State on 5-30-90 as an emergency; operative 5-30-90. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 3C).
7. Editorial correction of printing error in subsection (r) restoring HISTORY 5. and renumbering previous HISTORY 5. to 6. (Register 91, No. 32).

§ 6500.1. Effective Date of Repeal and Implementation.

NOTE: Authority cited: Section 208, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Amendment filed 8-29-80 as an emergency; effective upon filing (Register 80, No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed on 12-28-80.

3. Certificate of Compliance transmitted to OAL 12-15-80 and filed 1-21-81 (Register 81, No. 3).
4. Repealer filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

§ 6500.5. Definitions.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Renumbering and amendment of former Section 6500.5 to Section 6500 filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

§ 6501. Scope of Newborn Testing.

(a) Each newborn born in California shall be tested for hereditary hemoglobinopathies, phenylketonuria, hypothyroidism and galactosemia in accordance with procedures in this Article.

(b) The provisions of Section 6501 (a) shall not apply if a parent or legally appointed guardian objects to a test on the ground that it conflicts with his or her religious beliefs or practices. If the parent or legal guardian refuses to allow the collection of a blood specimen, such refusal shall be made in writing and signed by a parent or legally appointed guardian and included in the newborn's medical or hospital record.

(c) The provisions of Section 6501(a) shall not apply if the newborn has a condition almost certainly to be fatal in the first thirty (30) days of life which shall be documented in the medical record.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151, 154, 155, 309, 325, 326 and 327, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Amendment filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
3. Amendment of subsections (a) and (c) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6502. Laboratory Tests.

NOTE: Authority cited: Sections 151 and 208, Health and Safety Code. Reference: Section 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 1).
2. Repealer filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

§ 6502.1. Confidentiality.

(a) All information, records of interview, written reports, statements, notes, memoranda, or other data procured by an individual, group or research team in the course of any testing under this article shall be confidential and shall be used solely for the purposes of medical intervention, counseling, or specific research project approved by the Department.

(b) Except as provided by law, such information shall not be exhibited nor disclosed in any way, in whole or in part, by any individual, group, or research team except with the written consent of the person or his/her legally authorized representative unless such data can be made available in a manner which preserves anonymity of the persons tested.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 5-30-90 as an emergency; operative 5-30-90. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 30).

§ 6503. Newborn Screening Laboratories.

(a) The Department shall designate laboratories and tests to be used for Department required newborn tests. Such laboratories shall be either laboratories operated by the Department for quality control confirmatory and emergency testing or contractor laboratories licensed as clinical laboratories under the Business and Professions Code.

(b) Perinatal licensed health facilities and birth attendants shall submit required specimens to the newborn screening laboratory designated by the Department.

(c) Contract newborn screening laboratories shall be limited to laboratories that shall have submitted a bid acceptable to the Department on a competitive contract to provide laboratory services in sufficient volume to cover all of the newborns born in a geographical area, as defined by the Department, plus an appropriate emergency capacity. The Department will define not more than six areas and may combine areas if necessary to reduce costs or assure statewide coverage.

(d) Notwithstanding (c) above a comprehensive prepaid group practice direct health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available may have a laboratory serving a comprehensive prepaid group practice health care service plan designated a newborn screening laboratory under terms of a written agreement as defined in Section 6508(b) or may provide services in conformity with the terms of a mutually acceptable contract for services.

(e) Newborn screening laboratories shall participate in a proficiency testing program conducted by the Department's laboratory and shall maintain levels of performance acceptable to the Department.

(f) Newborn screening laboratories contracting with the Department shall be subject to on-site inspections and review of laboratory performance of tests and laboratory records.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Amendment filed 8-29-80 as an emergency; effective upon filing (Register 80, No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed 12-28-80.
3. Certificate of Compliance transmitted to OAL 12-15-80 and filed 1-12-81 (Register 81, No. 3).
4. Amendment filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
5. Amendment of subsections (d) and (e) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6504. Use of Newborn Screening Forms.

(a) All birth attendants engaged in providing perinatal care shall provide pregnant women, prior to the estimated date of delivery, with a copy of the informational material, titled "Important Information for Parents," provided by the Department.

(b) Perinatal licensed health facilities shall provide each pregnant woman admitted for delivery with a copy of the informational material provided by the Department, titled "Important Information for Parents," prior to collection of the blood specimen if such information has not been provided pursuant to subsection (a) above. If a woman is unable to read such material, it shall be translated or read to her in a language she understands.

(c) Department approved specimen collection forms shall not be copied, printed, reproduced, acquired, purchased or distributed other than as provided for in these regulations.

(d) Such Department approved specimen collection forms shall be fully and accurately completed by birth attendants, perinatal licensed health facilities and laboratories and a copy shall be filed in each newborn's medical record.

(e) Perinatal licensed health facilities shall maintain such records as are necessary to assure compliance with these regulations and provide the Department with such data as may be periodically required including, but not limited to, information on all newborns discharged or transferred from the facility without collection of a blood specimen. All such information and records shall be confidential but shall be open to examination by the Department personnel or its designated agents for any purpose directly connected with the administration of the newborn screening program.

(f) Birth attendants or physicians shall provide to parent(s) or legally appointed guardian(s) who object to the tests on the basis it is in conflict with their religious beliefs or practices, a refusal form approved by the Department and shall obtain the appropriate signature(s) upon the form. If the parent(s) or legally appointed guardian(s) is unable to read such material, it shall be translated or read to such person(s) in a language understood by such persons.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Amendment of subsection (f) filed 8-29-80 as an emergency (Register 80, No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed on 12-28-80.
3. Certificate of Compliance transmitted to OAL 12-15-80 and filed 1-12-81 (Register 81, No. 3).
4. Repealer and new section filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

§ 6505. Collection of Specimens.

(a) Birth attendants, laboratories and hospitals shall collect specimens using the technique for blood collection distributed by the Department.

(b) Physicians or birth attendants who are caring for newborns born in perinatal licensed health facilities shall have blood specimens collected using Department approved specimen collection forms in accordance with criteria distributed by the Department including the following:

(1) A specimen must be collected from any untested infant prior to blood transfusion.

(2) For newborns discharged before six days of age, a blood specimen shall be obtained as close to the time of discharge from the perinatal licensed health facility as is practical regardless of age or feeding history, unless the newborn is transferred for continuing care to another perinatal licensed health facility on or before the sixth day of age. Perinatal licensed health facilities which discharge infants before 24 hours of age may request a waiver from this requirement documenting how such newborns will be tested on or before 6 days of age. Such alternative testing schedules must be approved in writing by the Department.

(3) For newborns remaining in perinatal licensed health facilities beyond five days of age, a blood specimen shall be obtained from the newborn on the sixth day of age regardless of feeding history.

(4) For newborns received by transfer on or before six days of age, the receiving hospital shall obtain a blood specimen as close to discharge as possible, and if not discharged by the sixth day, a blood specimen shall be obtained on the sixth day of life.

(c) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility within the first six days of age, a specimen shall be obtained as close to discharge as possible, and if not discharged by the sixth day of life, a blood specimen shall be obtained on the sixth day of life unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.

(d) For newborns not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility after six days of age but within the first 30 days of age, a blood specimen shall be obtained within 48 hours after admission unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.

(e) Physicians attending sick newborns who exhibit symptoms suggestive of galactosemia, hypothyroidism or phenylketonuria (PKU), in addition to immediate diagnostic tests from local laboratory sources, shall have a blood specimen collected from the newborn and submitted to a newborn screening laboratory using forms purchased from the Department.

(f) Physicians attending critically ill newborns who require special care may postpone collection of a blood specimen until the newborn's emergency life threatening condition is stabilized.

(g) Birth attendants or physicians attending newborns not born in a perinatal licensed health facility and not subsequently admitted to a licensed health facility during the first six days of age, shall have a blood specimen collected from the newborn between the second and sixth days of age and submitted to a newborn screening laboratory using forms obtained from the Department.

(h) If a newborn is born outside of a perinatal licensed health facility and the birth is not attended by a birth attendant and the newborn is not subsequently admitted to a perinatal licensed health facility within the first ten days of age, the person required to register the birth shall arrange

for a blood specimen to be collected and submitted to a newborn screening laboratory between the second and tenth day of age.

(i) Initial specimens shall be collected using a Department-approved form and shall be placed in the United States mail or other approved channel of transmittal to the assigned Department-approved laboratory as soon as possible, but not later than 12 hours after they are obtained.

(j) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department approved scientific researchers without identifying the person or persons from whom these results were obtained, unless the person or his/her legally authorized representative specifically prohibits such use in writing.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15). For history of former section, see Registers 78, No. 34 and 74, No. 18.
2. Amendment of subsection (i) filed 8-29-80 as an emergency; effective upon filing (Register 80, No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed on 12-28-80.
3. Certificate of Compliance transmitted to OAL 12-15-80 and filed 1-12-81 (Register 81, No. 3).
4. Repealer and new section filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
5. Amendment of subsections (b), (c), (f) and (i), and new subsection (j) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6506. Reporting and Follow-Up of Tests.

(a) Perinatal licensed health facilities shall review each newborn's medical record within 14 days from the date of discharge to determine that the results of required tests are filed in the newborn's medical record, or that a parent's or legal guardian's signed refusal has been filed in the newborn's medical record.

(b) Whenever a perinatal licensed health facility determines that a discharged newborn has not received the mandated tests, the facility shall contact the newborn's physician by telephone to inform him/her that a specimen must be obtained and immediately send written notification to the newborn's physician and the Department. If the newborn's physician cannot be contacted or will not obtain a specimen, the perinatal licensed health facility shall notify the Department-approved area genetic center by telephone and shall send written notification within five days to the area genetic center and the Department.

(c) Whenever a perinatal licensed health facility determines that a specimen has been obtained, but there are no results available in the newborn's medical record the facility shall send written notification within five days to the Department.

(d) When the newborn's physician is notified by telephone by the perinatal licensed health facility that a newborn was discharged from the perinatal licensed health facility before a specimen was taken, the newborn's physician shall make every reasonable effort to have a specimen obtained within five days of notification. If the newborn's physician cannot obtain the specimen, the area genetic center shall be notified by the newborn's physician by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided.

(e) When a newborn's physician is notified by the laboratory by telephone that a specimen is inadequate, the physician so notified shall make every reasonable effort to have an adequate specimen obtained within five days of notification. If the newborn's physician so notified, cannot obtain the repeat specimen, the physician shall notify the area genetic center as soon as possible by telephone. Such telephone notification shall be noted in the newborn's physician's records specifying the date of notification, the person notified and the information provided.

(f) When the newborn's physician is notified by telephone by the Department-approved area genetic center of an initial presumptive positive test result the newborn's physician shall obtain an adequate recall blood specimen from the newborn and submit it to the designated laboratory

within 48 hours. If the recall blood specimen cannot be obtained within 48 hours, the newborn's physician shall notify the area genetic center by telephone. Such telephone notification shall be noted in the newborn's physician's records, specifying the date of notification, the person notified and the information provided.

(g) Repeat and recall specimens required by these regulations shall be collected on Department approved forms, placed in appropriate containers, and shall be placed in the United States mail or other approved channel of transmittal to the assigned, Department-approved laboratory as soon as possible, but not later than 12 hours after they have been obtained.

(h) All physicians making an initial diagnosis of a preventable heritable disorder for which testing is required under this Article shall report such diagnosis and the information necessary for follow-up and investigation to the Department.

(i) Willful or repeated failure to comply with these regulations shall be referred by any person having knowledge of non-compliance to the appropriate licensing authority. Failure to report may constitute grounds for disciplinary action including revocation of license.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New Section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Repealer and new section filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

§ 6507. Local Agencies Responsibilities.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Repealer and new section filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
3. Renumbering of Section 6507 to Section 6507.1 filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6507.1. Local Agencies Responsibilities.

(a) the county registrar shall provide a copy of the informational material prepared and provided by the Department to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility when the said newborn was not admitted to a perinatal licensed health facility within the first 30 days of age. The local health officer and the Department shall be notified of each such registration by the county registrar.

(b) Each local health department in the county where a newborn resides shall be responsible for making every reasonable effort to obtain specimens when requested by the Department-approved area genetic center or the Department. If after every reasonable effort a specimen cannot be obtained, the local health department may, after 30 days, with approval from the Department, terminate efforts.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. Renumbering of former Section 6507 to Section 6507.1 filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4). For prior history, see Register 86, No. 47.

§ 6507.2. Sickie Cell Education and Counseling Programs.

(a) Each sickie cell education and counseling program shall apply for and obtain written approval from the Department of Health Services. Such approval shall be contingent upon compliance with all sections of these regulations.

(b) Each sickie cell education and counseling program shall:

- (1) Provide counseling services to the clients.

(2) Employ State approved sickie cell counselors to perform all of the counseling following, or relating to, any abnormal hemoglobinopathy finding.

(3) Demonstrate, upon request by the Department of Health Services, that each of its counselors successfully participates in State-approved educational programs which serve to update the knowledge and enhance the proficiency of such counselors.

(4) Have a physician with special training and experience in pediatric hematology to serve as medical director or consultant to order and interpret laboratory tests used in counseling.

(5) Have written protocols to protect the confidentiality and security of all records containing personal information.

(6) Use only State-approved educational materials.

(7) Use any laboratory that meets the Department's standards for sickie cell hemoglobin testing.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 325, 326 and 327, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6507.3. Certificate of Approval As a Sickie Cell Counselor.

(a) A sickie cell counselor shall obtain a certificate of approval from the Department of Health Services upon presentation of written evidence that he or she has:

(1) Completed a course at a sickie cell counselor training center approved by the Department with such center's endorsement of his or her ability to function as a sickie cell counselor, and/or

(2) Successfully completed an examination or examinations which demonstrate his or her knowledge or expertise in the field, and one or more personal interviews to demonstrate an understanding of, and ability to communicate with persons who have sickie cell disease or sickie cell trait.

(b) All sickie cell counselors must provide documentation of completion of State-approved training to update skills and knowledge on an annual basis.

(c) This section shall not apply to physicians.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 325, 326 and 327, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).
2. Repealer of section 6507.3 and renumbering of section 6507.4 to section 6507.3 filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).

§ 6507.4. Voluntary Participation.

Participation by any person in a sickie cell education and counseling program in which medical information is obtained through interview, test or other ascertainment procedure shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other services or assistance from, or to participation in any other program.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Section 151, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).
2. Renumbering of section 6507.4 to section 6507.3 and renumbering of section 6507.5 to section 6507.4 filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.

3. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).

§ 6507.5. Informed Consent.

(a) A sickle cell education and counseling program shall obtain informed consent from each adult upon whom testing or any other screening procedure is to be performed. If the person is a minor other than a newborn, informed consent shall be obtained from such child's parent or guardian. An informed consent shall be obtained from an emancipated minor without the need for parent or guardian consent.

(b) The informed consent shall be in writing in format approved by the Department and shall be signed by the person, by his or her guardian or, except in the case of an emancipated minor, by his or her parent.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Section 151, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).
2. Renumbering of section 6507.5 to section 6507.4 and renumbering of section 6507.6 to section 6507.5 filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).
4. Editorial correction of HISTORY 2 (Register 95, No. 18).

§ 6507.6. Approval of Hemoglobin Counseling Laboratories.

(a) All laboratories that accept specimens from an approved sickle cell counseling program shall be in compliance with the Business and Professions Code governing licensed clinical laboratory operations and personnel (commencing with Section 1200 of the Business and Professions Code) or be an approved public health laboratory operated in accordance with the California Health and Safety Code, Section 1000 et seq.

(b) All laboratories involved in sickle cell screening as defined in these regulations shall use a test or combination of tests with demonstrated ability to distinguish hemoglobins including F, A, S, C, D, and E, as well as the thalassemias.

(c) The State Department of Health Services shall have the responsibility of monitoring sickle cell screening laboratories coming under the scope of these regulations. Such monitoring may be accomplished by on-site inspections and proficiency testing, or any other effective method. The Department may deny, revoke, or suspend the approval of any laboratory which does not comply or continue to comply with the above qualifications.

NOTE: Authority cited: Sections 208(a), 309 and 325, Health and Safety Code. Reference: Sections 325 and 327, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).
2. Renumbering of section 6507.6 to section 6507.5 and renumbering of section 6507.7 to section 6507.6 filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).

§ 6507.7. Sickle Cell Trait Follow-Up Vendor.

(a) A sickle cell trait follow-up vendor shall mean any sickle cell education and counseling program that is:

- (1) approved under this subchapter, and
- (2) signs a vendor agreement to provide services in accordance with Department policies, including a fee schedule provided by the Department. The Department may obtain and provide reimbursements for any or all follow-up services authorized as a result of newborn sickle cell screening from such approved vendors.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 325 and 326, Health and Safety Code.

HISTORY

1. Renumbering of section 6507.7 to section 6507.6 and new section filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.
2. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).

§ 6508. Fee Collection.

(a) Perinatal licensed health facilities and birth attendants shall obtain from the Department a sufficient supply of specimen collection forms to permit collection of a blood specimen from each newborn required to be tested under these regulations.

(b) The Department shall collect a fee for each specimen record form provided and a program participation fee for all services provided. The fee for a specimen record form shall be one (1) dollar and for program services forty-one (41) dollars except for a comprehensive prepaid group practice direct health care service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available* which elects to provide testing, follow-up and/or counseling services to its members. The fee for such plans shall be equal to the Department's cost of administration of the newborn screening program, to be determined by reducing the forty-one (41) dollar program service fee by the annual statewide average per infant contracted cost of laboratory testing, follow-up and/or counseling services rendered during the previous fiscal year. In order to qualify for this special fee a medical group serving a comprehensive prepaid group practice direct care service plan with 20,000 or more births shall sign a written agreement which contains the same standards and conditions, except as to payment or where specifically waived, as are applicable to the newborn screening laboratories and area genetic centers, adhere to the regulations governing the program, and to submit to monitoring and evaluation of compliance. Failure to comply with these conditions after being given written notification and thirty (30) days to correct deviations shall result in loss of the option. In the event the option is lost the State shall designate appropriate contractors to provide services.

The provisions of this section shall not apply if the newborn is part of a State-approved demonstration program.

(c) Birth attendants and physicians attending newborns who are under six days of age and who were not born in perinatal licensed health facilities and not subsequently admitted to perinatal licensed health facilities shall obtain a sufficient supply of specimen record forms to permit collection or shall arrange for a collection of a blood specimen from each such newborn attended.

(d) Birth attendants and physicians attending newborns and perinatal licensed health facilities shall not charge parents or third parties responsible for medical care coverage fees for participation in the newborn screening program in addition to those specified in this section, except for reasonable fees for costs of blood specimen collection and handling which shall not exceed six (6) dollars.

(e) The perinatal licensed health facility shall make available to the responsible physician, at no additional charge, specimen collection services or a specimen record form for obtaining either a repeat specimen for an inadequate specimen or a specimen on a newborn discharged without the test having been obtained.

(f) Birth attendants and physicians submitting a blood specimen for newborn screening on a form other than those approved by the Department shall be charged a handling fee of five (5) dollars in addition to the usual fee for program services and specimen record form specified in (b) above for each such specimen.

NOTE: Authority cited: Section 125000(h)(j), Health and Safety Code. Reference: Sections 125000(b) and 125005, Health and Safety Code.

HISTORY

1. New section filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).
2. Amendment filed 12-6-90 as an emergency print only; operative 12-6-90 (Register 91, No. 14). A Certificate of Compliance must be transmitted to OAL

- April 5, 1991, or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 12-6-90 order transmitted to OAL 3-19-91 and filed 4-8-91 (Register 91, No. 19).
 4. Amendment filed 8-7-91 by the Department of Health Services with the Secretary of State, operative 8-7-91. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 309 (Register 91, No. 50).
 5. Amendment of subsection (b) filed 6-30-92 with Secretary of State by the Department of Health Services; operative 7-1-92. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code sections 289.7(b) and 309(h) (Register 92, No. 27).
 6. Certificate of Compliance as to 6-30-92 order transmitted to OAL 10-20-92 and filed 11-20-92 (Register 92, No. 47).
 7. Editorial correction of HISTORY 5. (Register 92, No. 47).
 8. Amendment of subsections (b) and (f) and amendment of NOTE filed 6-6-97 as an emergency; operative 6-6-97 (Register 97, No. 24). This regulatory action is deemed an emergency exempt from OAL review and was filed directly with the Secretary of State pursuant to Health and Safety Code section 125000(h). These amendments shall remain in effect until revised or repealed by DHS pursuant to Health and Safety Code section 125000(j).

§ 6510. Rhesus (Rh) Hemolytic Disease of the Newborn.

(a) Medical staffs of hospitals and physicians thereof shall in providing for the care of pregnant women determine that a blood specimen has been obtained for the determination of rhesus (Rh) blood type or shall obtain or cause to be obtained a blood specimen within 24 hours of termination of pregnancy whether by delivery or by spontaneous or therapeutic abortion for this purpose as required by Article 2.7, Chapter 2, Part 1 of Division 1 of the Health and Safety Code.

(b) All cases, or suspected cases of rhesus (Rh) hemolytic disease of the newborn, shall be reported to the Department of Health Services. Every patient diagnosed in any licensed hospital as having such condition shall be reported by the hospital on the form provided by the Department for this purpose. The hospital shall notify the physician making the diagnosis that such a report has been filed.

NOTE: Authority cited: Sections 151, 208 and 306(b), Health and Safety Code.
Reference: Sections 304, 305 and 306, Health and Safety Code.

HISTORY

1. New section filed 3-16-70; effective thirtieth day thereafter (Register 70, No. 12).
2. Amendment of subsection (a)(1) filed 2-2-71; effective thirtieth day thereafter (Register 71, No. 6).
3. Editorial correction filed 11-5-84 (Register 84, No. 45).

Article 2. Testing of Pregnant Women for Heritable and Congenital Disorders

§ 6521. Definitions.

(a) Neural Tube Defects of the Fetus. "Neural tube defects of the fetus" means any malformation of the fetus caused by failure of the developing spine and skull to properly close. Examples are spina bifida and anencephaly.

(b) Birth Defects. "Birth defects" means any functional or structural defect caused by failure or error in the development of a fetus that is capable of being prenatally detected and for which the Department has provided a surveillance or screening program including but not limited to neural tube defects, ventral wall defects, and chromosomal defects.

(c) Expanded AFP Prenatal Screening for Birth Defects. "Expanded AFP prenatal screening for birth defects" means the sequence of screening tests of initial and repeat blood tests and, where medically indicated, differential diagnostic screening tests and procedures authorized by the Department and provided by department-approved vendors.

(d) Differential Diagnostic Screening Tests and Procedures. "Differential diagnostic screening tests and procedures" means those additional screening tests, methods, examinations or activities which are performed consequent to a positive blood screening test and which are used to distinguish between the presence of a birth defect of the fetus and other causes of positive blood screening tests.

(e) Gestational Age. "Gestational age" shall be defined as the number of days elapsed since the first day of the last normal menstrual period. Gestational age may be calculated as the number of days from known or suspected conception plus 14 days or by ultrasound examination and measurements.

(f) Alpha-fetoprotein. "Alpha-fetoprotein" means the protein substance in maternal serum and amniotic fluid, the concentration of which is tested to determine the probability that the fetus has a neural tube defect. For the purpose of these regulations, alpha-fetoprotein may be abbreviated and referred to as "AFP," maternal serum alpha-fetoprotein may be abbreviated and referred to as "MS-AFP," and amniotic fluid alpha-fetoprotein may be abbreviated and referred to as "AF-AFP."

(g) Analyte. "Analyte" means any constituent or substance the concentration of which is related to the presence of a birth defect and is analyzed and reported by prenatal screening laboratories as part of a departmentally provided or administered prenatal screening program including but not limited to alpha-fetoprotein, human chorionic gonadotrophin and estradiol.

(h) Method. "Method" means the steps and procedures used in a laboratory to measure the concentration of analytes in samples of maternal serum or amniotic fluid. Instruments, devices and reagents used are included in this definition.

(i) Expanded AFP Prenatal Birth Defects Screening Laboratory. "Expanded AFP prenatal birth defects screening laboratory" means a laboratory approved by the Department to conduct prenatal screening laboratory tests to determine the concentration of analytes and perform other analysis related to birth defects specified as part of state administered testing.

(j) Clinician. "Clinician" means physician, physician assistant, nurse midwife, nurse practitioner or any other person licensed or certified by the State to provide prenatal care to pregnant women or to practice medicine.

(k) Prenatal Diagnosis Center. "Prenatal diagnosis center" means any facility in California which is approved by the Department to provide differential diagnostic tests and procedures for the prenatal evaluation or detection of genetic diseases, disorders, and birth defects of the fetus.

(l) Initial Specimen. "Initial specimen" means the first adequate specimen collected from a pregnant woman pursuant to these regulations.

(m) Initial Screening Positive Test. "Initial screening positive test" means an initial screening test of a specimen which gives a positive result as defined by the Department for reporting purposes pursuant to these regulations.

(n) Inadequate Specimen. "Inadequate specimen" means a blood specimen collected from a pregnant woman which is not suitable in quality or quantity, was collected before the 105th or after the 140th day of gestation, or was not documented with the clinical information necessary for test result interpretation to perform valid prenatal screening for birth defects of the fetus.

(o) Repeat Specimen. "Repeat specimen" means a blood specimen collected from a pregnant woman following the screening laboratory report that a previously collected blood specimen was either inadequate or that the screening test results were screening positive or inconclusive as defined by the Department.

(p) An Expanded AFP follow-up vendor shall mean any facility, clinic, institution, health maintenance organization, or physician that:

(1) submits documentation verifying that it meets the standards published by the Department for approval as a comprehensive prenatal diagnosis center entitled: Prenatal Diagnosis Center Standards and Definitions 1997. This document in its entirety is hereby incorporated by reference in this section;

(2) has had the documentation verified by a state visit or;

(3) has had experience in the provision of follow-up of women with abnormal MS-AFP results as defined by California's MS-AFP Program prior to April 1, 1992; and

(4) receives notification of approval as a Prenatal Diagnosis Center; and

(5) signs a vendor agreement to provide such services in accordance with Department policies including a fee schedule published by the Department entitled: Vendor Agreement March 1, 1996, and incorporated by reference in these regulations. The Department may obtain and provide reimbursement for any or all follow-up services authorized as the result of MS-AFP screening from any or all such approved vendors.

NOTE: Authority cited: Sections 125000 and 125070, Health and Safety Code. Reference: Sections 124975-125050 and 125070, Health and Safety Code.

HISTORY

1. New article 2 (sections 6521-6529, not consecutive) filed by the Department of Health Services with the Secretary of State on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 86, No. 16).
2. Amendment of subsection (h) filed by the Department of Health Services with the Secretary of State on 6-16-88 as an emergency; effective 7-1-88. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 88, No. 27).
3. Certificate of Compliance as to 6-16-88 order transmitted to OAL 10-19-88 and filed 11-18-88 (Register 88, No. 48).
4. New subsections (n)-(n)(3) and amendment of NOTE filed 4-20-92 as an emergency; operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.
5. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8-17-92 and filed 9-28-92 (Register 92, No. 40).
6. Amendment of subsection (n)(1), new subsections (n)(2) and (n)(4), subsection renumbering and amendment of NOTE filed 10-1-92 as an emergency; operative 10-1-92 (Register 92, No. 40). Submitted to OAL for printing only pursuant to Government Code section 11343.8.
7. Certificate of Compliance as to 10-1-92 order filed 3-3-92 (Register 93, No. 10).
8. Amendment of section and NOTE filed 6-14-96 as an emergency; operative 6-14-96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
9. Editorial correction of HISTORY 8 (Register 97, No. 12).
10. Amendment of subsection (p)(1) filed 3-14-97 by the Department of Health Services with the Secretary of State; operative 3-14-97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97, No. 12).

§ 6523. Expanded AFP Prenatal Birth Defects Screening Laboratories and Analytical Methods.

(a) The Department shall approve Expanded AFP prenatal birth defects screening laboratories. Such laboratories shall be licensed as clinical laboratories under Division 2, Chapter 3 (commencing with Section 1200) of the Business and Professions Code.

(b) Approved Expanded AFP prenatal birth defects screening laboratories shall be limited to the following:

(1) A laboratory that shall have obtained a contract from the Department under applicable laws and regulations to provide laboratory services in sufficient volume to provide the prenatal birth defects screening test to all pregnant women in a designated geographic area defined by the Department, plus an emergency testing capacity that will be specified by contract. The Department will define not more than 6 geographic areas and may combine geographic areas if necessary to reduce costs or assure statewide coverage.

(2) A laboratory exclusively serving a comprehensive prepaid group practice or health care service plan with 25,000 or more births in the last completed calendar year for which complete statistics are available may be approved for testing consistent with the terms of a mutually acceptable contract for services.

(c) Expanded AFP prenatal birth defects screening laboratories approved by the Department shall comply with all laboratory standards for quality assurance issued by the Department and shall participate in a proficiency testing program approved and/or conducted by the Department and shall maintain levels of performance acceptable to the Department.

(d) Analytical methods to be used in the measurement of each analyte concentration in maternal serum shall be designated and/or approved by the Department.

(e) Analytical methods to be used in the measurement of the analyte concentration in amniotic fluid, and other adjunctive tests performed on amniotic fluid shall be designated and/or approved by the Department.

NOTE: Authority cited: Sections 125000(e) and 125070, Health and Safety Code. Reference: Sections 124980, 125000(e) and 125070, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 86, No. 16).
2. Amendment of section heading, section and NOTE filed 6-14-96 as an emergency; operative 6-14-96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
3. Editorial correction of HISTORY 2 (Register 97, No. 12).
4. Repeal of subsections (b)(3) and (f) filed 3-14-97 by the Department of Health Services with the Secretary of State; operative 3-14-97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97, No. 12).

§ 6525. Prenatal Diagnosis Centers and Laboratories.

The Department shall approve prenatal diagnosis centers and prenatal diagnosis methods and Expanded AFP Birth Defect Screening Laboratories and laboratory methods and shall institute such quality control and proficiency testing as is necessary to assure the accuracy of testing. No laboratory shall offer or provide prenatal birth defect screening diagnostic tests on California residents without having obtained prior approval from the Department.

NOTE: Authority cited: Sections 125050, 125055 and 125070, Health and Safety Code. Reference: Sections 124980, 125000 and 125070, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 86, No. 16).
2. Amendment of section heading, section and NOTE filed 6-14-96 as an emergency; operative 6-14-96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
3. Editorial correction of HISTORY 2 (Register 97, No. 12).

§ 6527. Clinicians.

(a) Clinicians shall provide or cause to be provided to all pregnant women in their care before the 140th day of gestation, or before the 126th day from conception, as estimated by medical history or clinical testing, information regarding the use and availability of prenatal screening for birth defects of the fetus. This information shall be in a format to be provided or approved by the Department and shall be given at the first prenatal visit and discussed with each pregnant woman.

(b) The provisions of subsection (a) shall not apply if the pregnant woman has completed more than 140 days of gestation or 126 days post conception, as estimated by medical history or clinical testing, and this fact is entered in the medical record.

(c) Clinicians shall cause to be provided to all pregnant women who, after being provided with the information pursuant to subsection (a), voluntarily request prenatal screening for birth defects of the fetus, the opportunity, the circumstances of which are to be documented in the medical record, to read and sign an informed consent document in a format provided or approved by the Department.

(d) If the pregnant woman consents to testing, the clinician shall arrange for prenatal screening directly or by referral to another clinician by:

(1) Fully and accurately completing all required specimen collection forms provided by the Department for this purpose;

(2) Collecting or arranging for the collection of an initial specimen following state directions for collection provided;

(3) As soon as possible, but within 24 hours of collection, place or cause to be placed all initial and repeat specimens in the channel of transmittal to the designated Expanded AFP prenatal birth defects screening laboratory.

(e) Blood collection forms and blood collection and mailing kits supplied by the Department shall not be copied, printed, reproduced, acquired, purchased, substituted or distributed other than as specified for use in the Expanded AFP Prenatal Birth Defects Screening Program administered by the Department.

(f) When notified that a blood specimen is inadequate for testing, the clinician shall make a reasonable effort to have an adequate specimen obtained as soon as possible but not more than five (5) days after such notification.

(g) For each woman in their care who was prenatally screened for birth defects of the fetus and who had an initial screening positive test, the clinician shall:

(1) Inform the woman that authorized follow-up services are available at Expanded AFP Follow-up Vendors, and that the program participation fees or laboratory test fee covers the authorized services.

(2) Report on the form provided by the Department for this purpose, within 30 calendar days of the end of the pregnancy, the outcome of pregnancy and status of each fetus, or infant resulting therefrom.

(h) The test results shall be confidential so that such information shall only be released with the knowledge and specific written consent of the woman tested. Persons authorized by the Department to conduct and monitor screening and/or to provide and monitor differential diagnostic follow-up services shall be provided information without necessity of specific written consent.

(i) Recognizing the strict gestational and time limits wherein prenatal detection of birth defects of the fetus is feasible, clinicians shall make every reasonable effort to schedule screening and differential diagnostic tests and procedures appropriately with respect to the gestational dates of the pregnant woman.

(j) Willful or repeated failure to comply with these regulations shall be referred by any person having knowledge of noncompliance to the appropriate licensing authority.

NOTE: Authority cited: Sections 12500 and 125070, Health and Safety Code. Reference: Sections 124980 (b), (c), (d), (h), (j) and 125070, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 86, No. 16).
2. New subsection (j) filed by the Department of Health Services with the Secretary of State on 6-16-88 as an emergency; effective 7-1-88. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 88, No. 27).
3. Certificate of Compliance as to 6-16-88 order transmitted to OAL 10-19-88 and filed 11-18-88 (Register 88, No. 48).
4. Amendment filed 8-7-91 by the Department of Health Services with the Secretary of State, operative 8-7-91. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 309 (Register 91, No. 50).
5. Amendment of section and NOTE filed 6-14-96 as an emergency; operative 6-14-96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
6. Editorial correction of HISTORY 5 (Register 97, No. 12).
7. Amendment of subsections (a), (c), (d)(1) and (d)(2), repealer of subsection (e), subsection relettering, and amendment of newly designated subsection (g)(1) filed 3-14-97 by the Department of Health Services with the Secretary of State; operative 3-14-97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97, No. 12).

§ 6529. Program Participation Fee.

(a) The Department shall collect an all-inclusive program participation fee for each screening service program. The fee for maternal serum alpha fetoprotein screening service for neural tube defects only shall be fifty-seven (\$7) dollars. The fee for maternal serum alpha fetoprotein and one or more additional analytes screening service for NTD and Down Syndrome shall be one hundred and fifteen (\$15) dollars. The fee shall be paid to the Department by the woman being tested or by any third party which is legally responsible for her care including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan as defined in or licensed in accordance with Health and Safety Code section 1340 et seq.

(b) Health care providers which contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership, may provide, without contracting with the Department, any or all of the testing and counseling services required to be provided under this section, if the services meet quality standards established by the De-

partment and the plan pays that portion of a fee established under this section which is directly attributable to the Department's cost of administering the testing or counseling service and any required testing or counseling services provided by the state for plan members during the previous fiscal year. This option must be executed under terms of a written agreement. Payment by the plan shall be deemed to fulfill any obligation the provider or the provider's patient may have to the Department to pay a fee in connection with the testing or counseling service.

NOTE: Authority cited: Sections 125070 and 125000(h)(j), Health and Safety Code. Reference: Sections 125000(b), 125005, 125050, 125055, 125060 and 125065, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 86, No. 16).
2. Amendment of subsection (a) filed by the Department of Health Services with the Secretary of State on 6-16-88 as an emergency; effective 7-1-88. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 88, No. 27).
3. Certificate of Compliance as to 6-16-88 order transmitted to OAL 10-19-88 and filed 11-18-88 (Register 88, No. 48).
4. Amendment filed 8-7-91 by the Department of Health Services with the Secretary of State; operative 8-7-91. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 309 (Register 91, No. 50).
5. Amendment of subsection (a) filed 6-30-92 with Secretary of State by the Department of Health Services; operative 7-1-92. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code sections 289.7(b) and 309(h) (Register 92, No. 27).
6. Certificate of Compliance as to 6-30-92 order transmitted to OAL 10-20-92 and filed 11-20-92 (Register 92, No. 47).
7. Editorial correction of HISTORY 5. (Register 92, No. 47).
8. Amendment of subsections (a) and (b) and amendment of NOTE filed 6-6-97 as an emergency; operative 6-6-97 (Register 97, No. 24). This regulatory action is deemed an emergency exempt from OAL review and was filed directly with the Secretary of State pursuant to Health and Safety Code sections 125000(h) and 125070(b). These amendments shall remain in effect until revised or repealed by DHS pursuant to Health and Safety Code sections 125000(j) and 125070(c).

§ 6531. Reporting of Neural Tube Defects.

(a) All cases of neural tube defect in a fetus or an infant under one year of age shall be reported to the Department. Neural tube defects shall mean any malformation of the fetus caused by the failure of the developing spine and skull to properly close.

(b) This report shall be made:

- (1) By the health facility in which the case is initially diagnosed;
- (2) By the physician making the initial diagnosis if the case is not diagnosed in a health facility;
- (3) Within 30 calendar days of the initial diagnosis;
- (4) On the form to be provided by the Department for this purpose.

NOTE: Authority cited: Section 289.7, Health and Safety Code. Reference: Section 289.7, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 10-9-85 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 85, No. 45).

§ 6532. Reporting of Chromosomal Disorders.

(a) All cases of Down's syndrome or other chromosomal defects in a fetus or an infant under one year of age shall be reported to the Department. Chromosomal defects shall mean any abnormality in structure or number of chromosomes.

(b) This report shall be made:

- (1) by the cytogenic laboratory performing the chromosomal analysis or by the physician making the diagnosis;
- (2) within 30 calendar days of the initial diagnosis;
- (3) on a form to be provided by the Department for this purpose.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Section 309, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 2-24-89 as an emergency; operative on 3-1-89. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 89, No. 10).